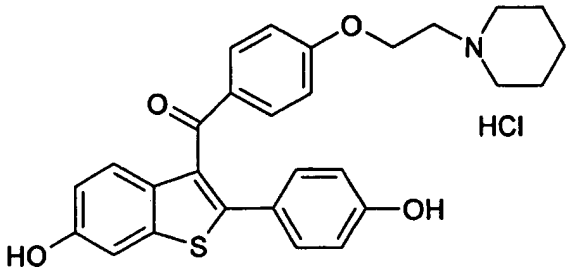
IN THE CLAIMS:

1.-25. (Cancelled)

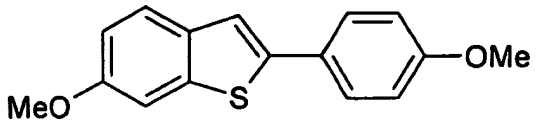
26. (Currently amended) Process for preparing raloxifene hydrochloride of formula (I)



(I)

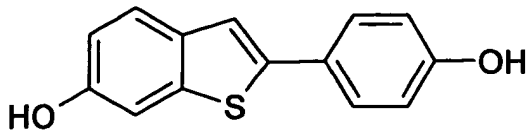
with a HPLC purity higher than 98% comprising the following stages:

a) demethylation of 6-methoxy-2-(4-methoxyphenyl)benzo[b]thiophene of formula (II)



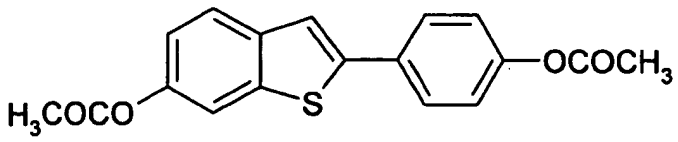
(II)

in pyridine hydrochloride to obtain 6-hydroxy-2-(4-hydroxyphenyl)benzo[b]thiophene of formula (III)



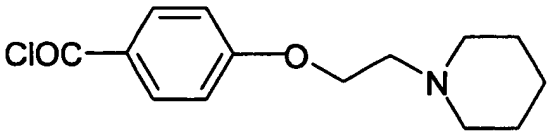
(III)

b) acetylation of 6-hydroxy-2-(4-hydroxyphenyl)benzo[b]thiophene with an acetylating agent to obtain the corresponding 6-acetoxy-2-(4-acetoxyphenyl)benzo[b]thiophene of formula (IV)



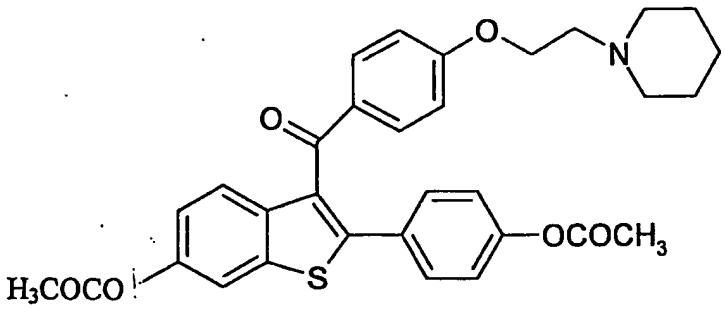
(IV)

c) acylation of 6-acetoxy-2-(4-acetoxyphenyl)benzo[b]thiophene (IV) with 4-(2-piperidinoethoxy)benzoylchloride hydrochloride of formula (V)



(V)

with aluminium chloride in halogenated solvent to obtain 6-acetoxy-2-(4-acetoxyphenyl)-3-[4-(2-piperidinoethoxy)benzoyl]-benzo[b]thiophene of formula (VI)



(VI)

d) hydrolysis of 6-acetoxy-2-(4-acetoxyphenyl)-3-[4-(2-piperidinoethoxy)benzoyl]-benzo[b]thiophene, according to the following operative modalities:

d1) treatment of 6-acetoxy-2-(4-acetoxyphenyl)-3-[4-(2-piperidinoethoxy)benzoyl]-benzo[b]thiophene with alkaline hydroxide in alcohol solvent,

d2) acidification of the product obtained in the preceding stage (d1) with a strong acid, to obtain the corresponding raloxifene salt with the strong acid,

wherein:

- stage (d1) is conducted using methanol as alcohol solvent and excess 30% sodium hydroxide;

- the strong acid used in stage (d2) is concentrated hydrochloric acid and said stage (d2) is conducted directly on the reaction mixture derived from stage (d1) to which equal weight quantities of water and ethyl acetate and finally 37% concentrated hydrochloric acid are added;

- the suspension obtained in stage (d2) is washed with equal weight quantities of water and ethyl acetate.

27. (Previously presented) Process as claimed in claim 26, wherein the pyridine hydrochloride used in stage (a) is prepared in situ by adding concentrated hydrochloric acid to pyridine and distilling off all the water to obtain a thick but stirrable residue.

28. (Currently amended) Process as claimed in claim 26, wherein the demethylation reaction of stage (a) of the process of the present invention is also conducted in the presence ~~or~~ of tributylamine.

29. (Previously presented) Process as claimed in claim 28, wherein tributylamine is used in weight ratios with respect to 6-methoxy-2-(4-methoxyphenyl)benzo[b]thiophene (II) of between 0.5 and 2.

30. (Previously presented) Process as claimed in claim 29, wherein stage (a) is conducted at a temperature between 170 and 180 °C.

31. (Previously presented) Process as claimed in claim 26, wherein acetic anhydride is used as acetylating agent in the presence of triethylamine in ethyl acetate.

32. (Previously presented) Process as claimed in claim 26, wherein the 4-(2-piperidinoethoxy)benzoylchloride hydrochloride of formula (V) used in stage (c) is

prepared in situ, by reacting 4-(2-piperidinoethoxy)benzoic acid hydrochloride with thionyl chloride in methylene chloride in the presence of pyridine, without isolating the reaction product.

33. (Previously presented) Process as claimed in claim 26, wherein stage (c) is conducted in methylene chloride.

34. (Previously presented) Process as claimed in claim 33, wherein stage (c) is conducted according to the following operative modalities: 6-acetoxy-2-(4-acetoxyphenyl)benzo[b]thiophene (IV) is added to non-isolated 4-(2-piperidinoethoxy)benzoylchloride hydrochloride of formula (V) and prepared in situ by reacting 4-(2-piperidinoethoxy) benzoic acid hydrochloride with thionyl chloride in methylene chloride in the presence of pyridine, without isolating the reaction product, and the aforesaid mixture is poured onto a mixture consisting of methylene chloride and aluminium trichloride.

35. (Previously presented) Process as claimed in claim 26, wherein the 6-acetoxy-2-(4-acetoxyphenyl)benzo[b]thiophene (IV) is not isolated, but is used in the crude state in the subsequent reaction (d).

36. (Previously presented) Process as claimed in claim 26, wherein raloxifene hydrochloride derived from stage (d2) is crystallised from an alcoholic solvent.

37. (Previously presented) Process as claimed in claim 36, wherein said solvent is methanol in the presence of HCl.

38. (Previously presented) Process as claimed in claim 36, wherein raloxifene hydrochloride is obtained with a purity greater than 99%.

39. (Previously presented) Process as claimed in claim 36, wherein a further crystallisation of raloxifene hydrochloride from alcohol solvent is conducted.

40. (Previously presented) Process as claimed in claim 39, wherein said crystallisation is conducted in methanol in the presence of HCl.

41. (Previously presented) Raloxifene hydrochloride with a purity greater than 99.7% and containing aluminium in a quantity less than 5 ppm %.

42. (Previously presented) Raloxifene hydrochloride as claimed in claim 41, containing raloxifene hydrochloride N-oxide in a quantity less than 0.05%.

43. (Previously presented) Raloxifene hydrochloride as claimed in claim 42, wherein said impurity is contained in a quantity less than 0.01%.

44.-46. (Cancelled)

47. (New) Process according to claim 38 wherein raloxifene hydrochloride has a $D(0.9) \leq 100$ μm and $D(0.5) \geq 40$ μm.

48. (New) Process according to claim 38 wherein raloxifene hydrochloride is subjected to sieving.

49. (New) Process according to claim 47 wherein raloxifene hydrochloride has a D(0.9) between 50 and 65 μm and $D(4.3) \geq 20$ μm.